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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/519,563	03/06/2000	Markus Haller	P-7354.03 CIP2	8702
27581	7590	07/20/2004	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			THOMPSON, MICHAEL M	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

YW

Office Action Summary

Application No.

09/519,563

Applicant(s)

HALLER ET AL.

Examiner

Michael M. Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/23/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

Claim Objections

2. Claims 1-27 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tucker (4,221,219) or Cummins (4,340,083) or DeCant, Jr. et al. (4,443,218) or Prosl et al. (4,541,429) or Wojcicki et al. (5,190,522) or Lord et al.

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(5,328,460) or Slettenmark (5,707,361). Tucker (4,221,219) and Cummins (4,340,083) and DeCant, Jr. et al. (4,443,218) and Prosl et al. (4,541,429) and Wojcicki et al. (5,190,522) and Lord et al. (5,328,460) and Slettenmark (5,707,361) all teach implantable medical devices for infusing comprising all of the limitations of the claims such as sealed means reservoir controlling means with pump and valves acting with piezoelectric elements inherently acting as deflectable electrical means (specifically Prosl et al. and Cummins) having energy storing means such as solenoids etc., wherein the methods are inherently a product of the structure. In the alternative, since it appears that Applicant has provided means plus function language that requires analysis of equivalents pursuant to the standards set forth in the MPEP and partially with respect to Applicant's own disclosure, it is the Examiner's position that any of the structures that Applicant believes are not explicitly recited in the references above have equivalent structures within the references. Since Applicant is one of ordinary skill in the art it is concluded that these equivalent structures will be readily evident upon analysis of each reference.

7. Claims 1-27 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jalink, Jr. et al. (6,071,087) similarly teaches an implantable medical device for infusing comprising all of the limitations of the claims such as sealed means reservoir controlling means with pump and valves acting with piezoelectric elements inherently acting as deflectable electrical means having energy storing means wherein the methods are inherently a product of the structure. In the alternative, since it appears that Applicant has provided means plus function language that requires analysis of equivalents pursuant to the standards set forth in the MPEP and partially with respect to Applicant's own disclosure, it is the Examiner's position that any of the structures that Applicant believes are not

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explicitly recited in the references above have equivalent structures within the references. Since Applicant is one of ordinary skill in the art it is concluded that these equivalent structures will be readily evident upon analysis of each reference.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,048,328. Although the conflicting claims are not identical, they are not patentably distinct from each other because the above mentioned claims recite substantially similar limitations of an implantable medical device for infusing comprising all of the limitations of the claims such as sealed means reservoir controlling means with pump and valves acting with piezoelectric elements inherently acting as deflectable electrical means having energy storing means.

10. Claims 1-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-55 of U.S. Patent No. 6,488,652. Although the conflicting claims are not identical, they are not patentably distinct from each other because similarly teaches an implantable medical device for infusing comprising all of the limitations of

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the claims such as sealed means reservoir controlling means with pump and valves acting with piezoelectric elements inherently acting as deflectable electrical means having energy storing means wherein the methods are further taught almost verbatim.

Response to Arguments

11. Applicant's arguments filed 04/23/04 have been fully considered but they are not persuasive. Applicant's arguments have failed to respond to the objections and therefore the rejections of record are maintained. On the outset, the Examiner would like to point out that an objection to the specification and claims was made in order to determine the metes and bounds of Applicant's means-plus-function language. The tone throughout each of the prior art rejections was intended to signal that the Examiner is unsure as to the metes and bounds of the claims when applying 112 sixth paragraph. MPEP 2181 was specifically recited to require Applicant to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element under the section provided, **“** WRITTEN DESCRIPTION ** NECESSARY TO SUPPORT A CLAIM LIMITATION WHICH INVOKES 35 U.S.C. 112, SIXTH PARAGRAPH.”** This section further recites, “The proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function.” Applicant's limitations recite, among other means language, “means for recovering the electric charge from the deflectable energy storing member” as Applicant has pointed out. Specifically, the recovery of charge from the deflectable energy storage member clearly borders on indefiniteness as it is unclear what structure, material, or acts

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will perform the recited function. It has been found that, “An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” (emphasis added)); see also *B. Braun Medical*, 124 F.3d at 1424, 43 USPQ2d at 1900 (holding that “pursuant to this provision [35 U.S.C. 112, sixth paragraph], structure disclosed in the specification is corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate structure to function is the quid pro quo for the convenience of employing 112, paragraph 6.”); *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542 (just because the disclosure provides support for a claim element does not mean that the USPTO cannot enforce its requirement that the terms and phrases used in the claims find clear support or antecedent basis in the written description. Therefore, it is the Examiner’s position that the prior art sufficiently meets that limitations of the claims in light of Applicant’s disclosure and the claims have been interpreted broadly. Several specific broad references have been recited to provide Applicant with the most comprehensive prior art. A similar determination has been made with respect to Double Patenting. The Examiner further maintains that it appears Applicant has acquiesced, at least, to the prior art rejections by not providing the necessary information to make a determination of equivalency not to mention the metes and bounds of the claimed subject matter. Therefore, this office action has been made Final on the merits as Applicant was provided the opportunity to respond in full.

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Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action. Please note that it appears, at minimum, Claim 27 has suffered from misspellings upon response.

Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson
Patent Examiner

MT
July 13, 2004


ANH TUAN T. NGUYEN
PRIMARY EXAMINER